

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., a
Japanese company;

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC., a
Delaware corporation

Defendant.

CIVIL ACTION NO. 1:21-CV-01015-LPS

OPPOSITION TO DEFENDANT'S MOTION TO DISMISS CLAIMS II-III

AND TO STRIKE SELECT PARAGRAPHS OF THE FIRST AMENDED COMPLAINT

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I. INTRODUCTION

Nippon Shinyaku¹ filed an amended complaint on September 10, 2021 (“Amended Complaint,” D.I. 39). Sarepta filed a motion to dismiss Claims II-III and to strike paragraphs of the Amended Complaint on September 24, 2021 (the “Motion,” D.I. 54). Sarepta’s Motion raises meritless jurisdictional arguments in an attempt to delay the progress of this case. Accordingly, Sarepta’s Motion should be denied.

First, with respect to Sarepta’s motion to strike, [REDACTED]

[REDACTED]

[REDACTED] Nippon Shinyaku’s [REDACTED]
[REDACTED] in its Amended Complaint is proper, including [REDACTED]
[REDACTED] its declaratory judgment claims (Claims II and III). [REDACTED]

[REDACTED] See D.I. 2, [REDACTED]

[REDACTED] The present action includes [REDACTED] [REDACTED] as well as claims for declaratory judgment of non-infringement and invalidity of Sarepta’s UWA Patents (Claims II and III), and claims directed at Sarepta’s infringement of the NS Patents (Claims IV-X). Nippon Shinyaku brought the present action to [REDACTED]

[REDACTED] District of Delaware, including its declaratory judgment claims. Nippon Shinyaku’s [REDACTED]
is thus expressly permissible and there is no basis for striking the disputed paragraphs in the Amended Complaint. Sarepta’s motion to strike should be denied.

Second, regardless of whether the challenged paragraphs are permitted or stricken, Nippon Shinyaku has sufficiently pled facts to sufficient to establish declaratory judgment jurisdiction

¹ Capitalized terms not otherwise defined have the same meaning as set forth in Nippon Shinyaku’s First Amended Complaint. See D.I. 39.

supporting Claims II and III. [REDACTED], Nippon Shinyaku has pled facts to demonstrate that Sarepta has charged Nippon Shinyaku with infringement of the UWA Patents, which alone is sufficient to provide declaratory judgment jurisdiction. [REDACTED] the Amended Complaint [REDACTED]

[REDACTED]. Those facts are sufficient to establish declaratory judgment jurisdiction.

Third, Sarepta challenges Claim II of the Amended Complaint (seeking declaratory judgment of non-infringement of the UWA Patents) for failure to state a claim under Rule 12(b)(6). However, Nippon Shinyaku has pled facts demonstrating that it (the manufacturer and seller of a pharmaceutical product) does not infringe UWA Patent claims at least because it does not practice the UWA Patent method of treatment claims. Such factual allegations are sufficient to establish at least one basis for non-infringement under Claim II. Since a motion to dismiss evaluates claims as a whole, rather than specific allegations, Nippon Shinyaku has sufficiently pled facts to support a plausible claim of non-infringement. Thus, Claim II—seeking a declaratory judgment of non-infringement—should also not be dismissed.

II. NATURE AND STAGE OF PROCEEDINGS

Nippon Shinyaku filed its Amended Complaint against Sarepta on September 10, 2021, asserting [REDACTED] claims for declaratory judgment of non-infringement and invalidity of Sarepta's UWA Patents (Claims II-III); and claims for Sarepta's infringement of the NS Patents (Claims IV-X). D.I. 39. Sarepta filed its Motion, D.I. 54, to dismiss Claims II-III of Nippon Shinyaku's Amended Complaint and to strike certain paragraphs of the Amended Complaint (including [REDACTED] as well as [REDACTED] [REDACTED] on September 24, 2021. Nippon Shinyaku opposes this Motion.

III. SUMMARY OF THE ARGUMENT

1. Sarepta's motion to strike paragraphs [REDACTED] should be denied because [REDACTED]

[REDACTED] D.I. 2, [REDACTED]

[REDACTED] Here, [REDACTED] of the Amended Complaint expressly [REDACTED] so the identified paragraphs are permitted. Moreover, Claims II and III both [REDACTED] [REDACTED] providing further basis for the inclusion of the identified paragraphs. Finally, paragraphs [REDACTED]

[REDACTED] There is no basis to strike such statements.

2. Sarepta's motion to dismiss Claims II-III of Nippon Shinyaku's Amended Complaint should be denied because Nippon Shinyaku has pled adequate facts to support declaratory judgment jurisdiction. The Amended Complaint includes allegations that Sarepta charged Nippon Shinyaku and its VILTEPSO[®] product of infringing the UWA Patents. *See Tabletop Media, LLC v. AMI Entm't Network, LLC*, No. 16-1121-RGA-MPT, 2017 U.S. Dist. LEXIS 166766, at *8 (D. Del. Oct. 10, 2017). Moreover, [REDACTED]

[REDACTED] This is sufficient to establish declaratory judgment jurisdiction.

3. Sarepta's motion to dismiss Claims II of Nippon Shinyaku's Amended Complaint should be denied because Nippon Shinyaku has pled adequate facts to support at least one theory of noninfringement. Specifically, Nippon Shinyaku is involved in the marketing and sale of VILTEPSO[®], which is a product that can be used to treat DMD. D.I. 39 at ¶ 79. Yet, certain claims of the UWA Patents cover a "method for treating a patient with [DMD]" that require "administering to the patient an antisense oligonucleotide." D.I. 2, Ex. K at Claim 1. As Nippon

Shinyaku is not a physician or healthcare provider administering VILTEPSO® but is instead involved in the marketing and sale of VILTEPSO®, it cannot directly infringe certain claims of the UWA Patents requiring a step of “administering to the patient an antisense oligonucleotide.”

IV. SAREPTA’S MOTION TO STRIKE UNDER RULE 12(F) SHOULD BE DENIED

“As a general matter, motions to strike under Rule 12(f) are disfavored.” *Vite Techs., LLC v. Smith & Nephew, Inc.*, No. 14-1507-SLR, 2015 WL 4486785, at *2 (D. Del. July 23, 2015).

Sarepta’s Motion seeks to strike certain paragraphs of the Amended Complaint that it argues are

[REDACTED], including [REDACTED]

[REDACTED] Paragraph 11 (D.I. 39 at ¶ 11) is representative, and states:

There is an actual case and controversy between Nippon Shinyaku and Sarepta regarding the UWA Patents that confers jurisdiction to this Court under 28 U.S.C. § 2201. The case or controversy is [REDACTED]

[REDACTED] This actual case and controversy [REDACTED]

Sarepta also seeks to strike [REDACTED]

[REDACTED] including [REDACTED]

[REDACTED]. These allegations relate to (i) [REDACTED]

[REDACTED],

(ii) [REDACTED]

[REDACTED], and (iii) [REDACTED]

[REDACTED].

A. [REDACTED]

First, Sarepta contends that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] D.I. 2, [REDACTED]³

1. **The Amended Complaint** [REDACTED]

Sarepta cannot and does not dispute that [REDACTED]

[REDACTED]

[REDACTED]. Thus, [REDACTED]

[REDACTED] Nippon Shinyaku has [REDACTED]

[REDACTED]

Sarepta argues that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Had the parties [REDACTED]

³ Emphasis added unless otherwise noted.

2. **Claims II And III Of The Amended Complaint Also** [REDACTED]
[REDACTED]

Regardless of the impact [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] including Nippon Shinyaku's
claims for declaratory judgment of non-infringement and invalidity of Sarepta's UWA Patents.

D.I. 2, [REDACTED] Because Claims II and III [REDACTED] [REDACTED]
[REDACTED]
[REDACTED].

Sarepta's attempts to distinguish Nippon Shinyaku's [REDACTED]
[REDACTED]

[REDACTED] Sarepta contends, without
support, [REDACTED]

However, [REDACTED]
[REDACTED]
[REDACTED] D.I. 2, [REDACTED]

This is [REDACTED]

In its Motion, Sarepta argues that [REDACTED]
[REDACTED]
[REDACTED].

[illegible]

Nippon Shinyaku's claims for declaratory judgment of non-infringement and invalidity of Sarepta's UWA Patents [REDACTED]

B.

[REDACTED]

[REDACTED]. Sarepta

argues that [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]. Sarepta is wrong. Contrary to

Sarepta's assertion, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3.

[REDACTED]

[REDACTED]

[REDACTED]

[illegible]

C.

As courts in this district have found, “even where the challenged material is redundant, immaterial, impertinent, or scandalous, a motion to strike should not be granted unless the presence of the surplusage will prejudice the adverse party.” *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353,

359 (D. Del. 2009). Sarepta does not dispute, and necessarily concedes, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Sarepta also cannot demonstrate any prejudice [REDACTED]

[REDACTED]

[REDACTED]

Moreover, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For these reasons, [REDACTED].⁵

⁵ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Accordingly, Sarepta’s motion to strike under Rule 12(f) should be denied.

V. SAREPTA’S MOTION TO DISMISS CLAIMS II AND III FOR LACK OF DECLARATORY JUDGMENT JURISDICTION UNDER RULE 12(B)(1) SHOULD BE DENIED

“Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to the court’s subject matter jurisdiction. In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. In this regard, the court must accept all factual allegations in the Complaint as true, and the court may only consider the complaint and documents referenced in or attached to the complaint.” *EchoStar Satellite LLC v. Finisar Corp.*, 515 F. Supp. 2d 447, 450 (D. Del. 2007). Here, Sarepta brings only a facial challenge—challenging the sufficiency of the pleadings, not the facts related to jurisdiction itself. Motion at 18 (“NS still does not sufficiently plead . . .”).

Courts have found that “there is no bright-line rule for determining whether [a declaratory judgment] action satisfies the case or controversy requirement.” *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1282 (Fed. Cir. 2012). Instead, the party seeking a declaratory judgment must demonstrate that the facts alleged, “show that there is a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory

judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). “Where one party asserts its patent rights against the other party’s product, and the other party contends that it can continue to create its product without a license, then there is a case or controversy because it creates a reasonable apprehension of infringement.” *Tabletop Media, LLC v. AMI Entm’t Network, LLC*, No. 16-1121-RGA-MPT, 2017 U.S. Dist. LEXIS 166766, at *8-9 (D. Del. Oct. 10, 2017).

Here, there is no question that Nippon Shinyaku has pled sufficient facts to establish declaratory judgment jurisdiction. Indeed, there is a substantial controversy as to whether whether Sarepta’s UWA Patents are invalid, and if not, whether VILTEPSO® infringes the UWA Patents. Sarepta seems to misconstrue the “immediacy” requirement and challenges whether there is a “supposed imminent infringement suit by Sarepta on the UWA Patents.” Motion at 18. But “the alleged infringing party does not need to risk an infringement suit before seeking a declaratory judgment.” *Tabletop Media*, 2017 U.S. Dist. LEXIS 166766, at *9. Instead, “[t]he immediacy requirement is concerned with whether there is an immediate impact on the plaintiff and whether the lapse of time creates uncertainty.” *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014). Here, Nippon Shinyaku has already received approval to and is marketing VILTEPSO®. D.I. 39 at ¶ 12. Thus, there is an immediate question as to whether VILTEPSO® infringes the UWA Patents, and there is no uncertainty regarding Nippon Shinyaku’s marketing of VILTEPSO®. This combination of facts establishes an actual case or controversy—something Sarepta cannot debate. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Moreover, it is irrelevant whether Sarepta has specifically threatened suit in the U.S. As the Federal Circuit has repeatedly held, “a specific threat of infringement litigation by the patentee is not required to establish jurisdiction, and a ‘declaratory judgment action cannot be defeated simply by the stratagem of a correspondence that avoids magic words such as ‘litigation’ or ‘infringement.’”” *Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1379 (Fed. Cir. 2011). Here, the totality of the circumstances supports declaratory judgment jurisdiction.

A. [REDACTED]

“If . . . a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction” at that time. *Tabletop Media*, 2017 U.S. Dist. LEXIS 166766, at *8 (quoting *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 96 (1993)). Here, [REDACTED]

[REDACTED]

The case or controversy [REDACTED]

[REDACTED] Nippon Shinyaku has sufficiently pled facts to support declaratory judgment jurisdiction of Claims II and III.

B. [REDACTED]

[REDACTED] provide a basis for declaratory judgment jurisdiction. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[illegible]

C. Jurisdiction Is Further Supported By The Amended Complaint

Finally, further factual allegations in the Amended Complaint also support declaratory judgment jurisdiction. [REDACTED]

First, the Amended Complaint

First, the Amended Complaint

contains allegations that the UWA Patents were specifically directed at capturing VILTEPSO®. D.I. 39 at ¶ 14. Sarepta demonstrated its intent to enforce these patents by listing the UWA Patents in the FDA Orange Book. *Id.* Moreover, [REDACTED]

[REDACTED] . And Sarepta [REDACTED]

[REDACTED] Under the circumstances, all of these facts support a finding of declaratory judgment jurisdiction. [REDACTED]

Based on the Amended Complaint, Nippon Shinyaku has sufficiently pled facts to support declaratory judgment jurisdiction of Claims II and III.

VI. SAREPTA’S MOTION TO DISMISS CLAIM II FOR FAILURE TO STATE A CLAIM UNDER RULE 12(B)(6) SHOULD BE DENIED

Sarepta also seeks to dismiss Claim II—Nippon Shinyaku’s claim for declaratory judgment of non-infringement of the UWA Patents—for failure to state a claim under Rule 12(b)(6). Motion at 7-11. Sarepta argues that Nippon Shinyaku’s allegations are “a mere denial” and are insufficient to state a claim. *Id.* (citing to allegations in D.I. 39 at ¶¶ 2, 89). Yet, Sarepta ignores other relevant facts contained in the Amended Complaint that establish that Nippon Shinyaku’s claim for declaratory judgment of non-infringement is plausible under the *Twombly/Iqbal* standard. *Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

Under the *Twombly/Iqbal* standard, a “claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. The defendant needs only to be given “‘fair notice of what the . . . claim is and the grounds upon which it rests.’” *Twombly*, 550 U.S. at 555

(quoting *Conley*, 355 U.S. at 47); *see also Iqbal*, 556 U.S. at 678 (“The plausibility standard is not akin to a ‘probability requirement’. . . .” (quoting *Twombly*, 550 U.S. at 556)). Determining whether a complaint states a plausible claim for relief is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679.

Based on this guidance, courts have found allegations in declaratory judgment noninfringement complaints sufficient under the *Twombly/Iqbal* standard when the plaintiff “has identified one of its products and the claim elements from [the] asserted patents that it believes are missing.” *Rain Gutter Pros, LLC v. MGP Mfg., LLC*, 55 F. Supp. 3d 1330, 1336 (W.D. Wash. 2014); *see also Cold Spring Granite Co. v. Matthews Int’l Corp.*, No. 10-cv-4272, 2011 WL 4549417 at *4 (D. Minn. June 1, 2011) (holding that “Plaintiff has stated a plausible claim for non-infringement [where] it has sufficiently identified and alleged the process and resultant product for which it seeks a declaratory judgment”); *Wistron Corp. v. Phillip M. Adams & Assocs., LLC*, No. 10-cv-4458, 2011 WL 1654466, *12 (N.D. Cal. Apr. 28, 2011) (noting that a declaratory judgment plaintiff only needs to “identify[] the accused products . . . to adjudicate an infringement claim”); *id.* (“*Twombly* is meant to weed out frivolous litigation where insufficient facts are alleged to form the basis for a claim, but should not be read to raise the pleading requirement to that of a summary judgment.” (internal quotation marks and citations omitted)).

Here, there is no question that Nippon Shinyaku has identified its product (VILTEPSO®) and patents at issue (Sarepta’s UWA Patents). *See* D.I. 39 at ¶¶ 79, 89 (identifying VILTEPSO® and the UWA Patents). [REDACTED]

[REDACTED]

[REDACTED] *Twombly*, 550 U.S. at 555; *see also Cold Spring Granite*, 2011 WL 4549417, at *5 (“[I]t is not readily apparent to the Court

why [Plaintiff's] description [of the accused product] does not fairly put Defendants on notice . . . for which Plaintiff seeks a declaratory judgment."); *id.* ("[C]ommon sense . . . compels the Court to conclude that Plaintiff has alleged with the requisite level of specificity and clarity the process for which it seeks a declaratory judgment."); [REDACTED]

[REDACTED] *Elan Pharma Int'l Ltd. v. Lupin Ltd.*, No. 09-cv-1008, 2010 WL 1372316, *5 (D.N.J. Mar. 31, 2010) ("Elan suffers no strategic disadvantage from this Court not ordering further factual support for Lupin's [declaratory judgment] counterclaims The crux of *Twombly* and *Iqbal* is to ensure that the defendant . . . has fair notice of what is being pled. Elan has that notice.").

Moreover, it is important to note, that in the context of declaratory judgments for non-infringement of patent, the Supreme Court has held that the filing of a declaratory judgment does not shift the burden of proof of infringement from the party alleging infringement to the party alleging non-infringement. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191 (2014). Thus, it is important that when applying the *Twombly/Iqbal* standard to an infringement complaint, courts only require "a brief description of what the patent at issue does, and an allegation that certain named and specifically identified products or product components also do what the patent does." *Bender v. LG Elecs. U.S.A., Inc.*, No. 09-cv-02114, 2010 WL 889541, at *6 (N.D. Cal. Mar. 11, 2010). Indeed, "a party need not plead facts supporting infringement allegations for each asserted claim seem to comport with the pleading standards set forth in *Twombly* and *Iqbal*." *Orion Energy Sys. v. Energy Bank Inc.*, No. 16-C-1250, 2017 U.S. Dist. LEXIS 174665, at *5 (E.D. Wis. Oct. 23, 2017); *see also Dynamic Data Techs., LLC v. Brightcove Inc.*, Civil Action No. 19-1190-CFC, 2020 U.S. Dist. LEXIS 127734, at *4 (D. Del. July 20, 2020).

Similarly, this Court has recently held that a claim survives if any part of that claim is plausible, regardless of whether certain theories espoused in the claim are supported by the allegations in the complaint. *See ECB USA, Inc. v. Savencia S.A.*, Civil Action No. 19-00731-RGA, 2021 U.S. Dist. LEXIS 186627, at *2 (D. Del. Sep. 29, 2021). In doing so, the Court noted that “[t]he complaint should not be ‘parsed piece by piece to determine whether each allegation, in isolation, is plausible.’” *Id.* (quoting *Sweda v. Univ. of Pennsylvania*, 923 F.3d 320, 331 (3d Cir. 2019)). Even though the Magistrate Judge recommended dismissing particular theories that had not met the pleading standard, the Court denied the motion to dismiss because “Plaintiffs have plausibly stated a claim for each count.” *Id.*

Thus, in order to survive dismissal of Claim II, Nippon Shinyaku need only to plead facts to support one theory of non-infringement. Nippon Shinyaku has done at least that. As pled throughout the Amended Complaint, Nippon Shinyaku is involved in the marketing and sale of VILTEPSO[®], which is a product that can be used to treat DMD. D.I. 39 at ¶ 79 (“Nippon Shinyaku . . . provide[s] antisense oligonucleotide-based therapies for the treatment of DMD. Sarepta and Nippon Shinyaku are the only companies with FDA clearance to market oligonucleotide therapies. . . . Nippon Shinyaku’s product is marketed under the name VILTEPSO[®].”); [REDACTED] (“[REDACTED]
[REDACTED]
[REDACTED].”).

At least certain claims of the UWA Patents cover a “method for treating a patient with [DMD]” that require “administering to the patient an antisense oligonucleotide.” D.I. 2, Ex. K at Claim 1. As Nippon Shinyaku does not administer VILTEPSO® but is instead involved in the marketing and sale of VILTEPSO®, it cannot directly infringe certain claims of the UWA Patents requiring a step of “administering to the patient an antisense oligonucleotide.” Accordingly, by

pleading that its actions with respect to VILTEPSO® involve marketing and selling, Nippon Shinyaku has sufficiently pled at least one basis for non-infringement of the UWA Patents. And as “[t]he complaint should not be ‘parsed piece by piece to determine whether each allegation, in isolation, is plausible,’” Nippon Shinyaku’s Amended Complaint contains sufficient facts to survive dismissal. *ECB*, 2021 U.S. Dist. LEXIS 186627, at *2 (quoting *Sweda*, 923 F.3d at 331). Thus, Sarepta’s motion to dismiss Claim II should be denied.

VII. TO THE EXTENT ANY PORTION OF SAREPTA’S MOTION IS GRANTED, NIPPON SHINYAKU SHOULD BE GRANTED LEAVE TO AMEND

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that after a responsive pleading has been filed, a party may amend its pleading “only with the opposing party’s written consent or the court’s leave,” and “[t]he court should *freely give leave* when justice so requires.” Fed. R. Civ. P. 15(a)(2). The Third Circuit has adopted a liberal approach to the amendment of pleadings. *See Dole v. Arco*, 921 F.2d 484, 487 (3d Cir. 1990). Accordingly, especially given that (1) Sarepta is not seeking dismissal *with prejudice* of any claims, and (2) the case is in the early stages and the parties are awaiting a Case Management Conference (to move forward with the non-contested claims, Claims I and IV-X), and as such there is no deadline for the amendment of pleadings, the Court should grant Nippon Shinyaku leave to amend its complaint if either of Claims II or III are dismissed based on Sarepta’s arguments.

VIII. CONCLUSION

For the above reasons, this Court should deny Sarepta’s motion to dismiss Claims II-III and Sarepta’s motion to strike under Rule 12(f).

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Respectfully submitted,

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